

Meeting Minutes

Handouts are not included with the minutes. If you need a copy of the handouts, please contact your Laboratory Division Director or Peggy DiNatale.

Item 3 was not discussed at this meeting and will be discussed at a future meeting.

1. QA Study Project related to specimens sent out to the CDC - proposed by Raimond Konomi

Raimond Konomi presented the data on the turn around time for specimens that the Virus Labs send to the CDC. For this data, the turn around time is defined as the time when the specimen was sent to the CDC by SLI and the time when a test report was received. The data showed that the turn around time for some tests was greater than 2 months.

The group discussed several areas of concern and discussed some potential reasons for the delays. These discussion points are briefly outlined below. At the conclusion of this portion of the discussion, Dr. Gilchrist indicated that she would contact the QI person at CDC to discuss the situation.

Discussion points:

- A. The CDC may look at some of these tests as being of epidemiological or research use and not consider them to be clinically useful.
- B. It is a difficult situation for the Virus lab staff when they can't tell the ordering physician when the test result can be expected to be completed.
- C. The Virus lab staff spends a lot of time calling the CDC to check on the status of the pending specimens, in addition to fielding calls from the ordering physician.
- D. The CDC may be using some acceptability criteria that is unknown to the SLI and when specimens don't meet the CDC criteria, the specimen may be held for testing at a later time. (ex. Onset date versus specimen collection date; symptoms)
- E. The CDC lab staff answering the calls may not have the ability or latitude to address some of the test reporting issues.
- F. There may be instances when the CDC reports are received at SLI and are not forwarded to the correct SLI laboratory for reporting. Currently CDC test reports are delivered to and sorted by an Administrative person who doesn't work in a lab. Currently the SLI Bacteriology labs are sending out some tests for viruses and the SLI Virus labs are sending out specimens for bacteria – this further complicates the triage process. Since some of the reports are complicated and rather busy, it is sometimes difficult to figure out what test was performed. This is presented as a process issue not a reflection on the person who is currently triaging these reports.

Raimond Konomi, Karen Chen, Sandy Smole and Peggy DiNatale met several times prior to this QI meeting to gather the data, analyze the data and develop some potential short term and long term solutions. They presented a list of potential short term solutions and a list of potential long term solutions.

Outcomes from this portion of the presentation are briefly outlined below.

Outcomes discussed:

- A. Sandra Smole, Infectious Disease Division Director, will call the CDC contacts for each Division to find out if there are defined specimen acceptability requirements for the tests that have extended turn around times.

- B. The Infectious Disease Division Director will designate one person who will be responsible for calling the CDC to follow up on pending specimens that are sent out by the Virus labs.
- C. All CDC test reports will be forwarded to Kathy Nawn. Kathy, having a lab background and being responsible for the Manual of Tests and Services, will forward the test reports to the appropriate lab.
- D. Kathy Nawn will update the list of send out specimens to ensure that it accurately reflects which SLI labs send out the various CDC specimens.
- E. The Reference lab, Enteric lab and TB lab will collect the turn around times for the CDC send outs for 2007. This information will be forwarded to Peggy DiNatale. Dr. Gilchrist will contact the QI person at CDC to see if this data may be useful to them.

NOTE: Update since QI meeting

SLI (Dr. Gilchrist, Dina Caloggero, Sandra Smole and Peggy DiNatale) participated in a conference call with Tom Hearn of the CDC to discuss the data compiled by the Virus lab and to open a dialogue with the CDC on this matter. We agreed that the SLI would compile data in a standard format from all of the labs and then send this data to Tom Hearn. We agreed to include a list of items identifying some consequences of delayed test results. Tom thanked us for collecting the data and for discussing the matter with him. We will work together and then at a later date we can share our experience with the other state laboratories, who may be encountering the same concerns.

This documentation was sent to Tom Hearn on March 26, 2008.

2. Overview of and Differentiation between Training / Competency Assessment / Annual Competency Assessment and How PT samples may be used to satisfy requirements for both PT testing and competency assessment

Two handouts were distributed and discussed. The first handout provides an overview of the CLIA and CAP regulations regarding proficiency testing. It includes guidance when in house PT surveys must be created and how PT samples can be incorporated into the competency assessment program.

The second handout provides an overview of a comprehensive Employee Competency Assessment Program which helps us maintain compliance with the CLIA regulations. The handout provides a brief description of the documentation needed for training a new employee, six month competency assessment for a new employee, one year competency assessment for a new employee and annual competency assessment for existing employees. The chart includes a brief description of some mechanism that can be used to assess competency at these various stages.

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3. Discussion of SOPs: Document control / SOP components / SOP Reviews / SOP Inventory List